

B1 cont. produce an antigen specific immune response when the Th2-immunostimulatory nucleic acid is administered mucosally or dermally.

2. The method of claim 1, wherein the subject is administered the antigen after the Th2-immunostimulatory nucleic acid.

3. The method of claim 1, wherein the subject is administered the antigen before the Th2-immunostimulatory nucleic acid.

4. The method of claim 1, wherein the subject is administered the antigen and the Th2-immunostimulatory nucleic acid simultaneously.

5. The method of claim 1, wherein the Th2-immunostimulatory nucleic acid is delivered to the mouth, skin or eye.

6. The method of claim 1, further comprising administering a therapeutic agent to the subject.

7. The method of claim 6, wherein the therapeutic agent is a Th1 adjuvant.

8. The method of claim 7, wherein the Th1 adjuvant is selected from the group consisting of CpG nucleic acids, MF59, SAF, MPL, and QS21.

9. The method of claim 7, wherein the Th1 adjuvant is administered following the administration of the Th2-immunostimulatory nucleic acid.

10. The method of claim 6, wherein the therapeutic agent is a Th2 adjuvant.

11. The method of claim 10, wherein the Th2 adjuvant is selected from the group consisting of adjuvants that create a depot effect, adjuvants that stimulate the immune system, and adjuvants that create a depot effect and stimulate the immune system and mucosal adjuvants.

12. The method of claim 11, wherein the adjuvant that creates a depot effect is selected from the group consisting of alum; emulsion-based formulations including mineral oil, non-mineral oil, water-in-oil or oil-in-water-in oil emulsion, oil-in-water emulsions such as Seppic ISA series of Montanide adjuvants; and PROVAX.

13. The method of claim 11, wherein the adjuvant that stimulates the immune system is selected from the group consisting of saponins purified from the bark of the *Q. saponaria* tree; poly[di(carboxylatophenoxy)phosphazene; derivatives of lipopolysaccharides, muramyl dipeptide and threonyl-muramyl dipeptide; OM-174; and Leishmania elongation factor.

14. The method of claim 11, wherein the adjuvant that creates a depot effect and stimulates the immune system is selected from the group consisting of ISCOMs; SB-AS2; SB-AS4; non-ionic block copolymers that form micelles such as CRL 1005; and Syntex Adjuvant Formulation.

15. The method of claim 11, wherein the mucosal adjuvant is selected from the group consisting of CpG nucleic acids, Bacterial toxins, Cholera toxin, CT derivatives, CT B subunit; CTD53; CTK97; CTK104; CTD53/K63; CTH54; CTN107; CTE114; CTE112K; CTS61F; CTS106; and CTK63, Zonula occludens toxin, zot, Escherichia coli heat-labile enterotoxin, Labile Toxin, LT derivatives, LT B subunit; LT7K; LT61F; LT112K; LT118E; LT146E; LT192G; LTK63; and LTR72, Pertussis toxin, PT-9K/129G; Toxin derivatives; Lipid A derivatives, MDP derivatives; Bacterial outer membrane proteins, outer surface protein A (OspA) lipoprotein of *Borrelia burgdorferi*, outer membrane protein of *Neisseria meningitidis*; Oil-in-water emulsions, Aluminum salts; and Saponins, ISCOMs, the Seppic ISA series of Montanide adjuvants, Montanide ISA 720; PROVAX; Syntex Adjuvant Formulation; poly[di(carboxylatophenoxy) phosphazene and Leishmania elongation factor.

16. The method of claim 6, wherein the therapeutic agent is a cytokine.

17. The method of claim 1, wherein the Th2-immunostimulatory nucleic acid is formulated in a form selected from the group consisting of a liquid solution, a powder, a microparticle, and a bioadhesive polymer.

18. The method of claim 1, wherein the Th2-immunostimulatory nucleic acid is administered by a route selected from the group consisting of oral, intranasal, vaginal, rectal, intra-ocular, and by inhalation.

19. The method of claim 1, wherein the Th2-immunostimulatory nucleic acid is administered by a route selected from the group consisting of intradermal, intraepidermal and transdermal.

20. The method of claim 1, wherein the antigen specific immune response is a systemic immune response.

21. The method of claim 1, wherein the antigen specific immune response is a mucosal immune response.

22. The method of claim 1, wherein the Th2-immunostimulatory nucleic acid is administered using a delivery system selected from the group consisting of a needleless delivery system, a scarification delivery system, and a tyne delivery system.

23. The method of claim 1, wherein the antigen is administered using a delivery system selected from the group consisting of a needleless delivery system, a scarification delivery system, and a tyne delivery system.

24. The method of claim 6, wherein the therapeutic agent is selected from the group consisting of an anti-viral agent, an anti-bacterial agent, an anti-parasitic agent, an anti-fungal agent, and cancer medicament.

25. The method of claim 1, wherein the antigen is selected from the group of antigens consisting of viral antigens, fungal antigens, bacterial antigens, parasitic antigens, and cancer antigens.

26. The method of claim 1, wherein the subject has not been exposed to an Th1 immunostimulatory nucleic acid prior to administration of the Th2 immunostimulatory nucleic acid.

27. The method of claim 1, wherein the subject is not experiencing a Th1 mediated disorder at the time of administration.

28. The method of claim 1, wherein the antigen is not conjugated to the Th2 immunostimulatory nucleic acid.

29. The method of claim 1, wherein the antigen is not a self antigen.

30. The method of claim 1, wherein the antigen is not an extracellular antigen.

B² 31. (Amended) A method for inducing an antigen specific immune response comprising: administering to a subject an antigen and a Th2-immunostimulatory nucleic acid, at least six nucleotides in length and having a phosphorothioate backbone linkage, in an amount effective to produce an antigen specific immune response when the Th2-immunostimulatory nucleic acid is administered parenterally.

52. The method of claim 31, wherein the subject has not been exposed to an Th1 immunostimulatory nucleic acid prior to administration of the Th2 immunostimulatory nucleic acid.

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100. (Amended) A pharmaceutical composition, comprising:
an effective amount of a Th2 immunostimulatory nucleic acid, at least six nucleotides in length and having a phosphorothioate backbone linkage, for stimulating a Th2 immune response when administered mucosally or dermally, an antigen, and a pharmaceutically acceptable carrier.

Remarks

The Examiner states in the present Office Action, page 2, that claim 1 has been amended by a response filed March 29, 2001. Applicants did not file a response on or near that time, nor